12 KAR 2:051. Manufacturing conditions.

RELATES TO: KRS 250.501, 250.511, 250.541, 250.551, 250.581(1), 21 C.F.R. 225.1-225.202, 226.1-226.115

STATUTORY AUTHORITY: KRS 250.541(c), 250.571(1), 21 C.F.R. 225.1-225.202, 226.1-226.115

NECESSITY, FUNCTION, AND CONFORMITY: KRS 250.571(1) authorizes the Director of the Agricultural Experiment Station to promulgate administrative regulations necessary for the efficient enforcement of KRS 250.491 to 250.631, regarding commercial feeds. KRS 250.541(2)(c) requires the promulgation of an administrative regulation that establishes the current good manufacturing practices for the manufacturing, processing, and packaging of commercial feed. This administrative regulation establishes current good manufacturing practices for feeds containing drugs or antibiotics.

Section 1. The current good manufacturing practices published in the Code of Federal Regulations for Type B and Type C medicated feeds are governed by:

(1) 21 CFR Part 225.1, Subpart A, 51 Federal Register 7389, March 3, 1986;

(2) 21 CFR Part 225.10, Subpart A, 42 Federal Register 12426, March 4, 1977;

(3) 21 CFR Parts 225.20, 225.30, 225.35, Subpart B, 41 Federal Register 52618, November 30, 1976;

(4) 21 CFR Part 225.42, Subpart C, 41 Federal Register 52618, November 30, 1976;

(5) 21 CFR Part 225.58, Subpart C, 55 Federal Register 11577, March 29, 1990;

(6) 21 CFR Part 225.65, Subpart C, 41 Federal Register 52618, November 30, 1976;

(7) 21 CFR Part 225.80, Subpart D, 41 Federal Register 52618, November 30, 1976;

(8) 21 CFR Parts 225.102 and 225.110, Subpart E, 41 Federal Register 52618, November 30, 1976;

(9) 21 CFR Part 225.115, Subpart E, 57 Federal Register 6475, February 25, 1992;

(10) 21 CFR Parts 225.120, 225.130 and 225.135, Subpart F, 41 Federal Register 52618, November 30, 1976;

(11) 21 CFR Parts 225.142, 225.158 and 225.165, Subpart G, 41 Federal Register 52618, November 30, 1976;

(12) 21 CFR Part 225.180, Subpart H, 51 Federal Register 7390, March 3, 1986; and

(13) 21 CFR Part 225.202, Subpart I, 51 Federal Register 7390, March 3, 1986.

Section 2. The current good manufacturing practices published in the Code of Federal Regulations for Type A medicated articles are governed by:

(1) 21 CFR Parts 226.1 and 226.10, Subpart A, 40 Federal Register 14031, March 27, 1975;

(2) 21 CFR Parts 226.20 and 226.30, Subpart B, 40 Federal Register 14031, March 27, 1975;

(3) 21 CFR Parts 226.40 and 226.42, Subpart C, 40 Federal Register 14031, March 27, 1975;

(4) 21 CFR Part 226.80, Subpart D, 40 Federal Register 14031, March 27, 1975; and

(5) 21 CFR Parts 226.102, 226.110 and 226.115, Subpart E, 40 Federal Register 14031, March 27, 1975. (AES-2 (1973)-10; 1 Ky.R. 1001; eff. 6-11-75; Am. 23 Ky.R. 1612; eff. 1-10-97; 25 Ky.R. 894; 2357; eff. 4-14-99.)